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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/109,858	07/02/98	RAO M	T5530.CIP

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JANE MASSEY LICATA, ESQ
LAW OFFICE OF JANE MASSEY LICATA
66 E. MAIN STREET
MARLTON NJ 08053

EXAMINER	
KERR, J	
ART UNIT	PAPER NUMBER
1633	19

DATE MAILED: 06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/109,858	Applicant(s) RAO ET AL.	
	Examiner Janet Kerr	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,15,16,21,23,24,26-33 and 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,15,16,21,23,24,26-33 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Response to Amendment

The amendment filed 3/30/01 has been entered.

Claim 44 has been canceled.

Claims 12, 15, 16, 21, 23, 24, 26-33, and 59 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 15, 16, 21, 23, 24, 26-33, and 59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (newly applied).

The claims are directed to methods of isolating a pure population of mammalian CNS neuron-restricted precursor cells and the precursor cells so obtained.

In the Office actions of 10/5/99 and 5/24/00, the reference of Blass-Kampmann *et al.* was applied to the claimed invention in a 35 U.S.C. 103(a) rejection in view of the teachings of Blass-Kampmann *et al.* of isolated precursor cells using an embryonic neural adhesion molecule antibody. It has been argued in applicants' Responses (Paper Nos. 9 and 13) and in a telephone interview conducted on 1/4/01 with Kathleen Tyrrell and Applicant Rao that the method of Blass-Kampmann *et al.* does not render the claimed invention obvious as the cells of Blass-Kampmann *et al.* do not have the claim-designated phenotype. It was indicated by Applicant Rao that the embryonic neural adhesion molecule antibody used was distinct from the antibody used in the instant invention as evidenced by the different precursor cell phenotypes obtained by the method of Blass-Kampmann *et al.* In view of this information, the specification is not enabling for the

claimed invention as the specification does not provide sufficient guidance for obtaining a embryonic neural adhesion molecule antibody which can be used in methods of isolating populations of cells expressing embryonic neural cell adhesion molecules such that the cells obtained fail to proliferate or differentiate in astrocyte-promoting medium containing FGF and 10% fetal calf serum. As the specification does not provide guidance as to how to make this antibody, and as it is not readily apparent that this antibody is readily available to the public, one of skill in the art could not practice the claimed invention. The requirements of 35 USC § 112, first paragraph may be satisfied by a deposit of the strains. The specification must contain the date that the antibody was deposited in an approved international patent culture depository, the name of the antibody and the complete address of where the antibody was deposited.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the antibody has been deposited under the Budapest Treaty and that **the antibody will be irrevocably and without restriction or condition released to the public upon the issuance of a patent**, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposit will be replaced if it should ever become inviable.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 15, 16, 21, 23, 24, 26-33, 44, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is rendered vague and indefinite by the phrase "NEP medium" as it is unclear what the components are in said medium. It is suggested that applicants define NEP medium in the claim. Claim 12 is also rendered vague and indefinite because it is unclear if in step (c) the cells are replated in the presence of a medium, and it is unclear in step (d) how the subpopulation of cells is purified, i.e., is an embryonic neural cell adhesion molecule antibody used?

Claims 21, 23, 24, and 59 are vague and indefinite as it is unclear how the cells are purified, i.e., is an embryonic neural cell adhesion molecule antibody used?

Claim 28 is rendered vague and indefinite as it is unclear what the source of the neuron-restricted precursor cells is, it is suggested that applicants include a first step of providing the cells and the method in which the the cells are obtained.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26 and 27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of copending Application No. 08/909,435 (newly applied). Although the conflicting claims are not identical, they are not patentably distinct from each other because the population of neuron restricted precursor cells of the instant invention is encompassed in the claimed pure population of rodent or human neuron restricted precursor cells of copending Application No.08/909,435.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet M. Kerr whose telephone number is (703) 305-4055. Should the examiner be unavailable, inquiries should be directed to Deborah Clark, Supervisory Primary Examiner of Art Unit 1633, at (703) 305-4051. Any administrative or procedural questions should be directed to Kimberly Davis, Patent Analyst, at (703) 305-3015. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must

conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is (703) 305-7401.

Janet M. Kerr, Ph.D.
Patent Examiner
Group 1600

DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600